Amarin Corporation

Amarin Announces Approval for Vascepa® in United Arab Emirates

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Approval is Second Middle East Country to Approve Vascepa Sale Following Lebanon Earlier This Year

BEDMINSTER, N.J. and DUBLIN, Ireland, July 26, 2018 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health, along with its commercial partner, Biologix FZCo, a pioneer in the distribution of pharmaceutical and biological products in the Middle East and North Africa (MENA) region, today announced that United Arab Emirates (UAE) Ministry of Health and Prevention has approved Vascepa® (icosapent ethyl) capsules as a prescription medication for use as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (TG > 500 mg/dL) hypertriglyceridemia in the UAE. This approval is a result of the collaborative effort by the parties since the start of their 2016 agreement to register and commercialize Vascepa in multiple countries in the MENA region.

"This approval to market Vascepa in the UAE was achieved sooner than originally expected," said John F. Thero, president and chief executive officer of Amarin. "The UAE represents the second of what we anticipate to be a number of approvals outside the United States to market and sell Vascepa. I thank Biologix for its positive initial execution on its plans to promote Vascepa in the MENA region."

Efforts are underway to gain approval to market and sell Vascepa in other countries in the MENA region. However, it is difficult to predict the timing of such approvals given the varied regulatory processes in each country. Amarin continues to anticipate that the revenue potential for Vascepa outside the United States will be relatively modest in 2018.

Under the previously announced collaboration agreement between Amarin and Biologix, Biologix is responsible for registering Vascepa in the MENA region, as well as providing all marketing, sales, and distribution services for the product. Amarin is responsible for providing regulatory assistance, supply and maintaining intellectual property in the region.

About Amarin

Amarin Corporation plc is a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health. Amarin's product development program leverages its extensive experience in lipid science and the potential therapeutic benefits of polyunsaturated fatty acids. Vascepa® (icosapent ethyl), Amarin's first FDA approved product, is a highly-pure, omega-3 fatty acid product available by prescription. For more information about Vascepa visit www.vascepa.com. For more information about Amarin visit www.amarincorp.com.

About Biologix FZCo

Biologix FZCO (Biologix) is a leading promoter and distributor of biotech products in the MENA region, based in Dubai, UAE. The company was founded in 2002 by Lebanese nationals and is serviced by Algorithm, a leading Lebanon based, pharmaceutical manufacturers company that has operations across the Middle East. Biologix offers regulatory, market access, medical, marketing, sales and distribution support to its partners with a direct presence in 17 countries of the Middle East and North Africa including Saudi Arabia, UAE, Kuwait, Iraq, Lebanon, Egypt, Algeria, and Morocco. Biologix focuses on the following therapeutics areas: oncology-hematology, cardio-metabolic, neurology, rare diseases and pain & inflammation.

About VASCEPA® (icosapent ethyl) Capsules

Vascepa® (icosapent ethyl) capsules are a single-molecule prescription product consisting of the omega-3 acid commonly known as EPA in ethyl-ester form. Vascepa is not fish oil, but is derived from fish through a stringent and complex FDA-regulated manufacturing process designed to effectively eliminate impurities and isolate and protect the single molecule active ingredient. Vascepa, known in scientific literature as AMR101, has been designated a new chemical entity by the FDA. Amarin has been issued multiple patents internationally based on the unique clinical profile of Vascepa, including the drug's ability to lower triglyceride levels in relevant patient populations without raising LDL-cholesterol levels.

FDA-Approved Indication and Usage

- Vascepa (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia.
- The effect of Vascepa on the risk for pancreatitis and cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined.

Important Safety Information for Vascepa

- Vascepa is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to Vascepa or any of its components.
- Use with caution in patients with known hypersensitivity to fish and/or shellfish.
- The most common reported adverse reaction (incidence > 2% and greater than placebo) was arthralgia (2.3% for Vascepa, 1.0% for placebo). There was no reported adverse reaction > 3% and greater than placebo.
- Patients receiving treatment with Vascepa and other drugs affecting coagulation (e.g., anti-platelet agents) should be monitored periodically.
- In patients with hepatic impairment, monitor ALT and AST levels periodically during therapy.
- Patients should be advised to swallow Vascepa capsules whole; not to break open, crush, dissolve, or chew Vascepa.

- Adverse events and product complaints may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.

FULL VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT WWW.VASCEPA.COM.

Vascepa has been approved for use by the United States Food and Drug Administration (FDA) as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. Nothing in this press release should be construed as promoting the use of Vascepa in any indication that has not been approved by the FDA.

Forward-Looking Statements

This press release contains forward-looking statements, including statements about the potential for successful development and commercialization of Vascepa in the MENA region; the efficacy, safety and therapeutic benefits of Vascepa and the commercial success of the collaboration effort and agreement; and the potential and timing for regulatory approvals and commercial opportunities that may result therefrom and in other territories outside the United States. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. Among the factors that could cause actual results to differ materially from those described or projected herein, including the ability to effectively commercialize Vascepa, will depend in part on the parties' ability to obtain necessary regulatory approvals in the MENA region, create market demand for Vascepa through education, marketing and sales activities, achieve market acceptance of Vascepa, receive adequate levels of reimbursement from third-party payers, develop and maintain a consistent source of commercial supply at a competitive price, and maintain patent and exclusivity protection. Other factors include uncertainties associated with clinical trials, regulatory reviews, commercial success, new collaborations and the ability of commercial partners to work together effectively to achieve intended results. A further list and description of these risks, uncertainties and other risks associated with an investment in Amarin can be found in Amarin's filings with the U.S. Securities and Exchange Commission, including its most recent quarterly report on Form 10-Q. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Amarin undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise.

Availability of Other Information About Amarin

Investors and others should note that Amarin communicates with its investors and the public using the company website (http://www.amarincorp.com/), the investor relations website (http://investor.amarincorp.com/), including but not limited to investor presentations and investor FAQs, Securities and Exchange Commission filings, press releases, public conference calls and webcasts. The information that Amarin posts on these channels and websites could be deemed to be material information. As a result, Amarin encourages investors, the media, and others interested in Amarin to review the information that is posted on these channels, including the investor relations website, on a regular basis. This list of channels may be updated from time to time on Amarin's investor relations website and may include social media channels. The contents of Amarin's website or these channels, or any other website that may be accessed from its website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

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